

--195. The medical balloon catheter of claim 188 wherein the first layer is biaxially oriented.--

--196. The medical balloon of claim 188 wherein the second layer is an adhesion layer.--

--197. The medical balloon of claim 196 wherein the adhesion layer is disposed toward the interior of the balloon relative to the second layer, which is disposed toward the exterior.--

--198. The medical balloon of claim 188 comprising a third layer.--

--199. The medical balloon of claim 198 wherein the third layer enhances lubricity and is disposed toward the exterior of the balloon relative to the first and second layer.--

REMARKS

Following the amendments above, claims 116, 118, 122-125, 127, 128, 133, 134, 140-143, 145, 146, 151, and 166-199 are pending, claims 116, 134, and 188 being independent and claims 166-199 being newly added. Applicant has amended the specification to correct the continuing data as requested by the Examiner. The indefiniteness rejection of claim 150 is now moot because claim 150 has been cancelled.

Applicant does not concede the Examiner's prior art rejections, however, to expedite prosecution applicant has amended the pending independent claims (claims 116 and 134) to recite that the first polymeric material is selected from the group consisting of polyetheretherketone (PEEK) and polyetherketone (PEK). Applicant reserves the right to pursue the subject matter of the previously pending claims at a later time.

Applicant has also added a new independent claim (claim 188) directed to the balloon catheter itself. Like amended independent claims 116 and 134, new claim 188 recites first and second extruded layers, with the first layer comprising a first polymeric material selected from the group consisting of polyetheretherketone (PEEK) and polyetherketone (PEK), and the second layer comprising a second polymeric material different from the first polymeric material.

Thus, all of the presently pending claims require that the first polymeric material be PEEK or PEK. Applicant's specification supports these particular embodiments of the invention at page 3, lines 14-36. As described therein, PEEK and PEK have suitable characteristics (e.g., high tensile strength and low distensibility) for the multilayer balloon.

The prior art cited by the Examiner, however, does not describe an extruded layer comprising PEEK or PEK. In particular, the Examiner pointed to column one of Patel (U.S. 4,335,723) and Levy (U.S. 4,490,421) to describe well known polymeric materials for a balloon (see page 10 of the Office

Action), but PEEK and PEK are noticeably absent from these references. For example, these references states:

Retention balloons have hitherto been made of thermoplastic materials such as polyethylene or plasticized polyvinyl chloride. (Patel at col. 1, lines 62-65)

Balloons can be made from a variety of known materials which are generally of the thermoplastic polymeric type. Included among the materials in the aforesaid patents are ethylene-butylene-styrene block copolymers admixed with low molecular weight polystyrene and, optionally, polypropylene, and similar compositions employing butadiene or isoprene in place of the ethylene and butylene; poly(vinyl chloride); polyurethanes; copolyesters; thermoplastic rubbers; siliconepolycarbonate copolymers; and ethylene-vinyl acetate copolymers. (Levy at col. 1, lines 29-39)

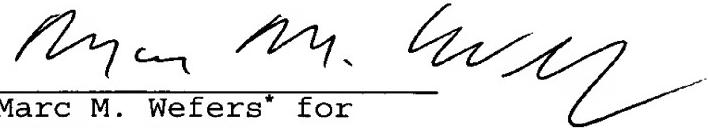
Moreover, these references do not describe or suggest an angioplasty balloon having multiple extruded layers with one of the layers comprising PEEK or PEK, as required by independent claims 116, 134, and 188.

In view of the above, applicant submits that all of the claims are in condition for allowance, which action is requested.

Enclosed is a Petition for Three Month Extension along with the required fee. Also enclosed is the required fee for the newly added claims. Please apply any fees not covered, or make any credits to Deposit Account 06-1050, referencing 10527/003005.

Respectfully submitted,

Date: 7/26/99

  
\_\_\_\_\_  
Marc M. Wefers\* for  
John J. Gagel  
Reg. No. 33,499

Fish & Richardson P.C.  
225 Franklin Street  
Boston, MA 02110-2804

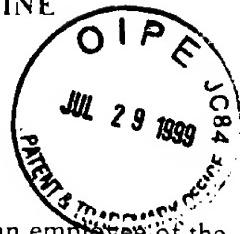
Telephone: 617/542-5070  
Facsimile: 617/542-8906

\* See attached document certifying that Marc M. Wefers has limited recognition to practice before the U.S. Patent and Trademark Office under 37 C.F.R. § 10.9(b).

373191.B11

UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE OFFICE OF ENROLLMENT AND DISCIPLINE

LIMITED RECOGNITION UNDER 37 CFR § 10.9(b)



Marc M. Wefers is hereby given limited recognition under 37 CFR § 10.9(b), as an employee of the Fish & Richardson, P.C., law firm, to prepare and prosecute patent applications and to represent patent applicants wherein the patent applicants are clients of the Fish & Richardson, P.C., law firm, and wherein a registered practitioner who is a member of the Fish & Richardson, P.C., law firm, is the attorney of record. This limited recognition shall expire on the date appearing below, or when whichever of the following events first occurs prior to the date appearing below: (i) Marc M. Wefers ceases to lawfully reside in the United States, (ii) Marc M. Wefers' employment with the Fish & Richardson, P.C., law firm, ceases or is terminated, or (iii) Marc M. Wefers ceases to remain or reside in the United States on an H-1B visa.

This document constitutes proof of such recognition. The original of this document is on file in the Office of Enrollment and Discipline of the U.S. Patent and Trademark Office.

Expires: September 16, 1999

Karen L. Bovard, Director  
Office of Enrollment and Discipline